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Date: October 18, 2004 Name: Nidia Deas Signature: Nidia Deas



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the Application	Edward L. Carver, Jr.	)	
of:	Steven J. Skiptunas	)	Group Art Unit: 1743
		)	
on:	APPARATUS AND	)	Examiner: L. Alexander
	METHOD FOR MIXING	)	
	FLUIDS FOR ANALYSIS	)	
		)	
Serial No.:	09/198,004	)	
		)	
Filed On:	November 23, 1998	)	(Docket No. 116310.0032)

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**APPELLANT'S APPEAL BRIEF**

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**I. INTRODUCTION**

In accordance with the provisions of 35 U.S.C. § 134 and 37 C.F.R. §§ 1.191 and 1.192, this Appeal Brief is submitted in triplicate in support of the appeal from the Office Action mailed on April 22, 2004, finally rejecting claims 1, 3-6, 31 and 33-47.

**A. Real Party In Interest**

The real party in interest (and owner) is Drew Scientific Group Plc.

**B. Related Appeals and Interferences**

None.

**II. STATUS OF THE CLAIMS**

**A. Status of Pending Claims**

Claims 1, 3-6, 31 and 33-47 are pending in this application. Claims 1, 3-6, 31 and 33-47 have been finally rejected under both 35 U.S.C. § 102(b) and 35 U.S.C. § 102(e) and each of these claims are on appeal.

**B. Status of Canceled Claims**

The subject application, U.S. Patent Application Serial No. 09198,004 was filed on November 23, 1998. The subject application was filed with thirty nine (39) claims.

In a Preliminary Amendment, mailed on November 23, 1998, original claims 7-30 were canceled and new claims 40-43 were added. In an Amendment mailed on August 9, 1999 claims 2 and 32 were cancelled. Thus, the following claims have been canceled during prosecution of the subject application and are not on appeal herein: claims 2, 7-30 and 32.

### **III. STATUS OF THE AMENDMENTS**

There were no amendments filed subsequent to the final rejection of this application. Appellant filed a Response To Office Action (Final Rejection) under 37 C.F.R. § 1.116 on March 17, 2004, offering arguments to surmount the rejection. An Advisory Action was then issued stating that the arguments contained in the response failed to overcome the rejections.

### **IV. SUMMARY OF THE INVENTION**

Appellant's claimed invention is directed to apparatus and methods for analysis of reagent mixtures. A first apparatus is for analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood. The apparatus includes (1) means for pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate, (2) means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream, (3) means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture, and (4) means for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream.

A second apparatus is for analysis of reagent mixtures having a plurality of reagent-mixture components. The apparatus includes (1) means for pumping each of a plurality of reagent-mixture components in a respective stream at a respective flow rate, (2) means for introducing at least one reagent-mixture component into a stream of at least one other reagent-mixture component to mix the plurality of reagent-mixture components into a combined reagent-mixture stream, and (3) means coupled in fluid communication with the outlet port

for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the combined reagent-mixture stream. The means for introducing includes (a) an elongated mixing chamber defining an upstream end, a downstream end, and an elongated axis extending between the upstream and downstream ends, (b) a first inlet port located at the upstream end of the mixing chamber and coupled in fluid communication with the pumping means, and defining a first inlet axis for introducing a first reagent-mixture component stream into the mixing chamber along the first inlet axis, (c) a second inlet port located downstream of the first inlet port and coupled in fluid communication with the pumping means, and defining a second inlet axis for introducing a second reagent-mixture component stream into the mixing chamber along the second inlet axis, wherein one of the first and second inlet axes is inclined at an acute angle relative to the other and the elongated axis for introducing the respective reagent-mixture component stream into the mixing chamber in a different flow direction than the other reagent-mixture component stream to thereby create turbulence in the combined reagent-mixture stream, and (d) an outlet port located downstream of the inlet ports for receiving the combined reagent-mixture stream.

The method is for analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood. The method includes (1) pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate, (2) combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream to mix the plurality of reagent-mixture components and create a combined reagent-mixture stream, (3) forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture, and (4) analyzing the components of each selected reagent mixture.

**V. ISSUES**

The issue raised in the Final Rejection requiring resolution in this Appeal is as follows:

Whether claims 1, 3-6, 31 and 33-47 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0107333.

Whether claims 1, 3-6, 31 and 33-47 are properly rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,380,491.

Whether claims 1, 3-6, 31 and 33-47 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,030,888.

**VI. GROUPING OF CLAIMS**

The claims on appeal before the Board of Patent Appeals and Interferences are claims 1, 3-6, 31 and 33-47. Claims 1, 3-6, 40 and 42-47 relate to apparatus for analysis of reagent mixtures having a plurality of reagent-mixture components. Claims 31, 33-39 and 41 relate to methods for analysis of reagent mixtures having a plurality of reagent-mixture components.

The claims on appeal are set forth in the Appendix, and the independent claims 1, 31 and 42 are set forth below:

1. An apparatus for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood, comprising:

means for pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate;

means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream;

means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture; and

means for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream.

31. A method for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood, comprising the steps of:

pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate;

combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream to mix the plurality of reagent-mixture components and create a combined reagent-mixture stream;

forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture; and

analyzing the components of each selected reagent mixture.

42. An apparatus for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components, comprising:

means for pumping each of a plurality of reagent-mixture components in a respective stream at a respective flow rate;

means for introducing at least one reagent-mixture component into a stream of at least one other reagent-mixture component to mix the plurality of reagent-mixture components into a combined reagent-mixture stream, said means including:

an elongated mixing chamber defining an upstream end, a downstream end, and an elongated axis extending between the upstream and downstream ends,

a first inlet port located at the upstream end of the mixing chamber and coupled in fluid communication with the pumping means, and defining a first inlet axis for introducing a first reagent-mixture component stream into the mixing chamber along the first inlet axis,

a second inlet port located downstream of the first inlet port and coupled in fluid communication with the pumping means, and defining a second inlet axis for introducing a second reagent-mixture component stream into the mixing chamber along the second inlet axis, wherein one of the first and second inlet axes is inclined at an acute angle relative to the other and the elongated axis for introducing the respective reagent-mixture component stream into the mixing chamber in a different flow direction than the other reagent-mixture component stream to thereby create turbulence in the combined reagent-mixture stream, and

an outlet port located downstream of the inlet ports for receiving the combined reagent-mixture stream; and

means coupled in fluid communication with the outlet port for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the combined reagent-mixture stream.

Pursuant to 37 C.F.R. § 1.192(c)(7), Appellant hereby groups the pending claims for purposes of appeal as follows:

Claims 1, 3-6, 40 and 45-46 stand rejected under 35 U.S.C. § 102(b) as anticipated by EP ‘333, and USP ‘888, and rejected under 35 U.S.C. § 102(e) as anticipated by USP ‘491.

Rejected claims stand or fall together

Claims 31, 33-39 and 41 stand rejected under 35 U.S.C. § 102(b) as anticipated by EP ‘333, and USP ‘888, and rejected under 35 U.S.C. § 102(e) as anticipated by USP ‘491.

Rejected claims stand or fall together

Claims 42-44 stand rejected under 35 U.S.C. § 102(b) as anticipated by EP ‘333, and USP ‘888, and rejected under 35 U.S.C. § 102(e) as anticipated by USP ‘491.

Rejected claims stand or fall together

## **VII. ARGUMENT**

Claims 1, 3-6, 31 and 33-47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0107333 (hereinafter “EP ‘333”). Claims 1, 3-6, 31 and 33-47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,030,888 (hereinafter “USP ‘888”). Claims 1, 3-6, 31 and 33-47 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,380,491 (hereinafter “USP ‘491”). The



Examiner's grounds for rejection are hereinafter traversed, and allowance respectfully requested, in view of the arguments below.

**A. EP '333 Does Not Teach or Suggest The Invention Recited in Claim 1.**

The Examiner asserts at paragraph 10 of the second Advisory Action mailed on April 22, 2004, that "The Office maintains the art teaches a "mixture" in the conventional meaning when viewed macroscopically," and hence "The art teaches a flow with different components which has been properly read on the claimed mixture." The Applicants' respectfully maintain that the Office has not properly considered the claim language "mixture" in accordance with its well known meaning and the art of record teaches away from making a mixture as claimed. In particular, it is submitted that the Examiner has not correctly interpreted the claim language in accordance with the plain and ordinary meanings of the words used. Independent claim 1 recites "means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream". (Emphasis added). The ordinary meaning of "combining" is "To join (two or more substances) to make a single substance, such as a chemical compound; mix." (The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company). The ordinary meaning of "stream" is "A steady current of a fluid." (*Id.*) And the ordinary meaning of "mixing" is "To combine or blend into one mass or mixture." (*Id.*) Thus, the ordinary meaning of the recited function is to combine (or join or mix to make a single substance or compound) at least one reagent-mixture component stream (i.e., a steady current of fluid) into a stream of at least one other reagent-mixture component for mixing (i.e., to combine or blend into one mass or mixture) the plurality of reagent-mixture components into

a combined (i.e., mixed into a single substance or compound) reagent-mixture stream. For example, at page 4, lines 3-6 of the present application, the Applicants state that “The flow-injection unit injects at least one reagent-mixture component into a stream of at least one other reagent-mixture component to mix the components and create a selected reagent mixture.” (Emphasis added). This is fully commensurate with the plain and ordinary meaning of “mixing” (i.e., to combine or blend into one mass or mixture). The present application does not assign any different meanings to these words recited in the claim, but rather uses the words in a manner entirely consistent with their plain and ordinary meanings.

Accordingly, contrary to the statement at page 3 of the Action mailed November 17, 2003, it is respectfully submitted that the Applicant’s remarks are entirely commensurate in scope with the pending claims.

The undersigned respectfully disagrees with the Examiner’s statement at page 3 of the Action mailed November 17, 2003 that “The instant claim language of mixture is interpreted as a composition of different components, which clearly reads on the taught sheath fluid/blood/reagent mixture.” First, the claim language should be interpreted in accordance with the plain and ordinary meanings of the words used as set forth above. Second, the claim does not recite a “composition of different components”, and therefore this interpretation may unnecessarily confuse the issue. In any event, a “composition” is defined as “a mixture or compound”. (*Id.*) A “mixture” is defined as “The act or process of mixing . . .; The condition of being mixed . . .” (*Id.*) Contrary to the Examiner’s assertion at page 3 of the Action, EP ‘333 does not teach or suggest any such feature. Rather, as set forth clearly in Applicant’s Response filed August 27, 2003, EP ‘333 explicitly teaches not to mix the concomitant flows prior to or during analysis.

In addition, the Examiner's statement at page 3 of the Action mailed November 17, 2003 that the claim language "does not specify anything about the status of the mixture in a flow cell or when the samples are mixed" is not correct. Independent claim 1 recites:

"means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream;" and

"means for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream". [Emphasis added].

Thus, the claim necessarily requires that the reagent-mixture component streams first be combined and mixed into the combined reagent-mixture stream. Then, the combined reagent-mixture stream is analyzed in the flow cell or like means. Independent claims 31 and 42 recite commensurate limitations. EP '333, on the other hand, specifically teaches away from these claim limitations. As set forth in detail in Applicant's Response filed August 27, 2003, EP '333 explicitly teaches not to mix the concomitant flows prior to and during analysis within the flow cell. Accordingly, EP '333 teaches away from the combination as properly interpreted and recited in independent claim 1.

Contrary to the Examiner's assertion at pages 3 and 4 of the Action mailed November 17, 2003, the quoted passage at pages 4 and 5 of EP '333 does not teach or suggest "a mixture of first and second fluids simultaneously through the flow cell". As set forth above, the plain and ordinary meaning of "mixture" is "The act or process of mixing . . .; The condition of being mixed . . . ." (*Id.*) Neither this passage nor any other in EP '333 teaches mixing the concomitant flows in the sheath stream flow cell. Rather, EP '333 specifically teaches maintaining the sample and sheath fluid in two separate unmixed streams that are concentrically located at two different diameters. For example, EP '333 states: "the sheath

stream flow cell 12 brings the sample and sheath streams introduced at inlets 26 and 28, respectively together to form a pair of concentric, substantially unmixed streams, with the sample stream at the center." (Page 7, lines 7-12 of EP '333, emphasis added). EP '333 further states: "This forms the concentric sample-sheath liquid streams through the flow cell under precisely controlled and coordinated, readily reproducible conditions of constant, and optimal, sample and sheath liquid stream diameters . . . ." (EP '333 at page 14, lines 4-7, emphasis added). Thus, the concentric sample-sheath liquid streams are not mixed prior to or during analysis in the flow cell, but rather are mixed only when discarded as waste in the flow cell outlet. Indeed, the very purpose of maintaining the separate, unmixed streams as taught by EP '333 is to facilitate analysis in the flow cell. It is respectfully submitted that the Examiner must view each prior art reference in its entirety and for its teachings as a whole, and the clear teaching of the EP '333 is away from the presently claimed invention.

Accordingly, it is respectfully submitted that EP '333 wholly fails to teach or suggest the invention as recited in independent claim 1 for at least these reasons.

**B. EP '333 Does Not Teach or Suggest The Invention Recited in Claim 42.**

EP '333 does not teach or suggest the combination of "means for introducing at least one reagent-mixture component into a stream of at least one other reagent-mixture component to mix the plurality of reagent-mixture components into a combined reagent-mixture stream" and "means ... for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the combined reagent-mixture stream", as recited in claim 42.

As stated above, although EP '333 shows three blood sample-reagent mixtures and three sheath liquids (each of the three sheath liquids being optically compatible with a respective one of the blood sample-reagent mixtures), none of the blood sample-reagent

mixtures is combined with any of the other blood sample-reagent mixtures. Further, the blood sample-reagent mixture and respective sheath liquid are maintained in separate, unmixed streams prior to and during analysis in the sheath stream flow cell, and are not mixed until after they exit the flow cell and are discarded as waste. Although EP '333 describes concomitant flow of a blood sample-reagent mixture and its respective sheath liquid, this does not in any way teach or suggest introducing "to mix ... into a combined ... stream", as recited in claim 42. Indeed, EP '333 explicitly teaches not to mix the concomitant flows, and therefore teaches away from the claimed invention. Thus, EP '333 cannot possibly teach or suggest the combination recited in independent claim 42.

Accordingly, it is respectfully submitted that EP '333 wholly fails to teach or suggest the invention as recited in independent claim 42 for at least these reasons.

**C. EP '333 Does Not Teach or Suggest The Invention Recited in Claim 31.**

EP '333 does not teach or suggest "forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture", as recited in claim 31.

As stated above with respect to claim 1, EP '333 forms different selected reagent mixtures by pre-mixing them in the reaction vessels. There is simply no teaching or suggestion in EP '333 of forming such mixtures by combining reagent-mixture streams, much less adjusting the flow rates of the components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture. Thus, EP '333 cannot possibly teach or suggest the combination recited in independent claim 31.

Accordingly, it is respectfully submitted that EP '333 wholly fails to teach or suggest the invention as recited in independent claim 31 for at least these reasons.

**D. USP '888 Does Not Teach or Suggest The Invention Recited in Claims 1 and 42.**

USP '888 does not teach or suggest the combination of “means for combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream”, as recited in claims 1 and 42. USP '888 teaches an automatic blood analyzer that is fixed to make the same dilution ratios, with the same volumes of reagent-mixture components for every blood sample. In addition, the fixed reagent mixtures are mixed in typical cuvette-type chambers, such as the chambers 6 and 11 of FIG. 1. There is no teaching or suggestion of combining one stream (i.e., “a steady current of a fluid”) into another stream to create a combined reagent-mixture stream, as recited in claims 1 and 42. Furthermore, after the samples and lysing agents are mixed by pouring into the cuvettes, they are poured out of, or pumped out of the cuvettes, and passed through a sensing cell for analysis. Thus, USP '888 does not teach a means for combining one reagent-mixture component stream into another reagent-mixture component stream and forming a combined reagent-mixture component stream, as recited in independent claims 1 and 42. Rather, the reagent mixture components are poured into a cuvette, and mixed within the cuvette, not combined into a combined reagent-mixture stream, as recited in claims 1 and 42.

The Examiner incorrectly dismisses these clear and unambiguous limitations of the claim at page 4 of the Action mailed on November 17, 2003, on grounds that they recite a “method of intended use” and are of “no patentable moment.” As set forth in Applicant’s

Response filed August 27, 2003, independent claims 1 and 42 recite clear and unambiguous structural limitations that are drafted in “means-plus-function” language under 35 U.S.C. § 112. Accordingly, these recitations must be construed to cover the structure disclosed in the specification for performing the recited functions and equivalent structure. 35 U.S.C. § 112. Thus, the functional recitations in the claims are not merely a “method of intended” use as asserted by the Examiner. Rather, these limitations must be properly construed under § 112, and must be given “patentable moment” in distinguishing over the cited references.

Accordingly, it is respectfully submitted that USP ‘888 wholly fails to teach or suggest the invention as recited in independent claims 1 and 42 for at least these reasons.

**E. USP ‘491 Does Not Teach or Suggest The Invention Recited in Claims 1 and 42.**

USP ‘491 does not teach or suggest the combination of “means for combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream”, as recited in claims 1 and 42. USP ‘491 discloses the mixing of the blood sample with lysing agent A and/or lysing agent B in a typical mixing cuvette 13. The samples and lysing agents are poured into and mixed in the cuvettes. There is again no teaching or suggestion of combining one stream (i.e., “a steady current of a fluid”) into another stream to create a combined reagent-mixture stream, as recited in claims 1 and 42. Furthermore, after the samples and lysing agents are mixed by pouring into the cuvettes, they are poured out of, or pumped out of the cuvettes, and passed through a sensing cell for analysis. Thus, USP ‘491 does not teach a means for combining one reagent-mixture component stream into another reagent-mixture component stream and forming a combined reagent-mixture

component stream, as recited in independent claims 1 and 42. Rather, the reagent mixture components are poured into a cuvette, and mixed within the cuvette, not combined into a combined reagent-mixture stream, as recited in claims 1 and 42. Again, the Examiner incorrectly dismisses these clear and unambiguous limitations of the claims at page 4 of the Action mailed on November 17, 2003 on grounds that they recite a “method of intended use” and are of “no patentable moment.” As set forth in Applicant’s Response filed August 27, 2003, independent claims 1 and 42 recite clear and unambiguous structural limitations that are drafted in “means-plus-function” language under 35 U.S.C. § 112. Accordingly, these recitations must be construed to cover the structure disclosed in the specification for performing the recited functions and equivalent structure. 35 U.S.C. § 112. Thus, the functional recitations in the claims are not merely a “method of intended” use as asserted by the Examiner. Rather, these limitations must be properly construed under § 112, and must be given “patentable moment” in distinguishing over the cited references.

Accordingly, it is respectfully submitted that USP ‘491 wholly fails to teach or suggest the invention as recited in independent claims 1 and 42 for at least these reasons.

**F. Neither USP ‘888 nor USP ‘491 Teach or Suggest The Invention Recited in Claim 31.**

Neither USP ‘888 nor USP ‘491 teach or suggest the pumping of reagent-mixture streams and combining them into a combined reagent-mixture stream. To the contrary, both USP ‘888 and USP ‘491 disclose that the samples and lysing agents are poured into and mixed in the cuvettes (not pumped in streams that are combined and mixed into a combined reagent-mixture stream), and then after they are mixed, they are poured out of, or pumped out of the cuvettes, and passed through a sensing cell for analysis. Furthermore, the cited



references do not teach or suggest -- and the Office Action mailed November 17, 2003 does not state otherwise -- adjusting the flow rates of the components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture, as also recited in independent claim 31.

Accordingly, it is respectfully submitted that both USP '888 and USP '491 wholly fail to teach or suggest the invention as recited in independent claims 31 for at least these reasons.

**G. Conclusion**

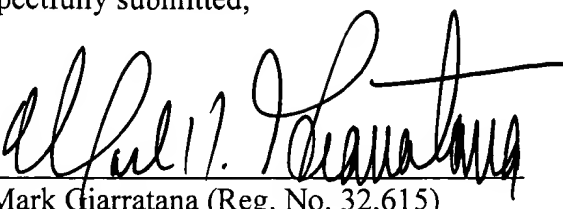
It is respectfully submitted that independent claims 1, 31 and 42 are not anticipated by EP '333, USP '888 and USP '491 for at least these reasons. Because claims 3-6, 33-41 and 43-47 each depend from, and therefore include all of the limitations of one of these independent claims, it is respectfully submitted that these dependent claims likewise are also patentable over the EP '333, USP '888, and USP '491 references.

Accordingly, for the foregoing reasons, reversal of the Final Rejection of claims 1, 3-6, 31 and 33-47 is warranted and such action is earnestly solicited.

The Commissioner is hereby authorized to charge payment under small entity status for filing a brief in support of an appeal of \$170 pursuant to 37 C.F.R. § 1.17(c), and for an extension for response within the third month of \$490 pursuant to 37 C.F.R. § 1.17(a)(3) for a total payment amount of \$660 to deposit account no. 50-1402. No additional fee is believed to be required in connection with this filing. However, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 50-1402.

Respectfully submitted,

October 16, 2004

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**VIII. APPENDIX**

The pending claims are as follows:

1. An apparatus for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood, comprising:

means for pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate;

means for combining at least one reagent-mixture component stream into a stream of at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream;

means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture; and

means for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream.

3. An apparatus as defined in claim 1, wherein the means for pumping includes a plurality of pumps, each pumping a respective reagent-mixture component, and the means for forming each of a plurality of different selected reagent mixtures is coupled to and controls the flow rate of each pump to, in turn, control the flow rate of at least one of the plurality of reagent-mixture components in accordance with the flow-rate ratio of the reagent-mixture components corresponding to a selected reagent mixture.

4. An apparatus as defined in claim 3, further comprising a plurality of pump motors, each pump motor being coupled to a respective pump to control the flow rate of the pump and a respective reagent-mixture component.
5. An apparatus as defined in claim 1, wherein the means for forming comprises a control unit coupled to the means for pumping and including a database of predetermined reagent-mixture ratios, wherein each predetermined reagent-mixture ratio corresponds to one or more animal species, and the control unit is responsive to an input for a selected animal species to control the means for pumping to pump the reagent-mixture components of the respective reagent-mixture ratio of the selected animal species at a flow-rate ratio corresponding to the reagent-mixture ratio.
6. An apparatus as defined in claim 1, further comprising a plurality of reagent-mixture component chambers, wherein each reagent-mixture component chamber contains a respective reagent-mixture component and is coupled in fluid communication with the means for pumping for supplying reagent-mixture components to the means for pumping.
31. A method for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components including a sample of blood, comprising the steps of:
  - pumping each of a plurality of reagent-mixture components including the sample of blood in a respective stream at a respective predetermined flow rate;
  - combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream to mix the plurality of reagent-mixture components and create a combined reagent-mixture stream;

forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture; and

analyzing the components of each selected reagent mixture.

33. A method as defined in claim 31, wherein each flow-rate ratio of the reagent-mixture components is approximately equal to the mixture ratio of the respective reagent mixture.

34. A method as defined in claim 31, further comprising the steps of creating a database including a plurality of predetermined reagent-mixture ratios, wherein each reagent-mixture ratio corresponds to one or more species, and creating a reagent mixture for each of a plurality of selected species by pumping the reagent-mixture components of the reagent-mixture ratio for a selected species at a flow-rate ratio corresponding to the respective reagent-mixture ratio.

35. A method as defined in claim 34, wherein the flow-rate ratio is approximately equal to the respective reagent-mixture ratio for each selected species.

36. A method as defined in claim 31, further comprising the step of directing the plurality of reagent-mixture components in the combined reagent-mixture stream through a tortuous path to facilitate mixing the reagent-mixture components into a selected reagent mixture.

37. A method as defined in claim 31, further comprising the step of accelerating and decelerating the flow rate of the reagent-mixture components in the combined reagent-mixture stream to facilitate mixing the reagent-mixture components into a selected reagent mixture.

38. A method as defined in claim 31, further comprising the step of directing the combined reagent-mixture stream through a flow path defined by relatively expanded and relatively constricted portions to facilitate mixing the reagent-mixture components into a selected reagent mixture.

39. A method as defined in claim 31 for hematology testing and analyzing particle distributions within the reagent mixtures for blood cell analysis, comprising the steps of pumping a plurality of reagent-mixture components selected from the group including (i) a whole blood sample of a selected species, (ii) diluent, and (iii) a lysing agent, and forming a blood/diluent/lyse reagent mixture corresponding to the selected species.

40. An apparatus as defined in claim 1, wherein the means for forming forms the selected reagent mixture by adjusting the flow rates of at least two reagent-mixture components in accordance with the respective flow-rate ratio.

41. A method as defined in claim 31, comprising the step of forming each reagent mixture by adjusting the flow rates of at least two reagent-mixture components in accordance with the respective flow-rate.

42. An apparatus for at least one of particle and chemical analysis of reagent mixtures having a plurality of reagent-mixture components, comprising:

means for pumping each of a plurality of reagent-mixture components in a respective stream at a respective flow rate;

means for introducing at least one reagent-mixture component into a stream of at least one other reagent-mixture component to mix the plurality of reagent-mixture components into a combined reagent-mixture stream, said means including:

an elongated mixing chamber defining an upstream end, a downstream end, and an elongated axis extending between the upstream and downstream ends,

a first inlet port located at the upstream end of the mixing chamber and coupled in fluid communication with the pumping means, and defining a first inlet axis for introducing a first reagent-mixture component stream into the mixing chamber along the first inlet axis,

a second inlet port located downstream of the first inlet port and coupled in fluid communication with the pumping means, and defining a second inlet axis for introducing a second reagent-mixture component stream into the mixing chamber along the second inlet axis, wherein one of the first and second inlet axes is inclined at an acute angle relative to the other and the elongated axis for introducing the respective reagent-mixture component stream into the mixing chamber in a different flow direction than the other reagent-mixture component stream to thereby create turbulence in the combined reagent-mixture stream, and

an outlet port located downstream of the inlet ports for receiving the combined reagent-mixture stream; and

means coupled in fluid communication with the outlet port for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the combined reagent-mixture stream.

43. An apparatus as defined in claim 42, wherein the second inlet port is angularly spaced relative to the first inlet port and defines a second inlet axis oriented transverse to the elongated axis, and the second inlet port is coupled in fluid communication with the pumping means for introducing a second reagent-mixture component stream into the mixing chamber in a different flow direction than the first reagent-mixture component stream to thereby create turbulence in the combined reagent-mixture stream.

44. An apparatus as defined in claim 42, further comprising means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture.

45. An apparatus as defined in claim 1, wherein the means for forming comprises a control unit electrically coupled to the means for pumping to set the flow rates of the reagent-mixture components in accordance with the flow-rate ratio of each selected reagent mixture.

46. An apparatus as defined in claim 45, wherein the control unit includes a database of information pertaining to the flow-rate ratios of the reagent-mixture components of the selected reagent mixtures.



47. An apparatus as defined in claim 1, wherein the means for combining includes a mixing chamber, a plurality of inlet ports coupled in fluid communication between the mixing chamber and the means for pumping for introducing the reagent-mixture components into the mixing chamber, and at least one outlet port coupled in fluid communication between the mixing chamber and the means for analyzing for introducing the combined reagent-mixture stream into the means for analyzing.

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